March 8, 2022

Ulike Co., Ltd
℅ Bryan Wong
Associate, RAC
PureVision Ai, Inc.
111 Town Square Place, Suite 1203
Jersey City, New Jersey 07310

Re: K213558
Trade/Device Name: IPL Hair Removal Device
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONF
Dated: November 8, 2021
Received: November 8, 2021

Dear Bryan Wong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva Pandya
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213558

Device Name
IPL Hair Removal Device

Indications for Use *(Describe)*
The IPL Hair Removal Device (Model: UI04A, UI04B, UI04C) is indicated for patient removal of unwanted hair by using a selective photothermal treatment under the direction of a physician, after training by a healthcare professional. The IPL Hair Removal Device is also intended for permanent reduction in unwanted hair.
Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6. 9. and 12 months after the completion of a treatment regimen.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

Sponsor	
Company Name	Ulike Co., Ltd
Address	2, Myeongdong, 6-gil, Jung-gu, Seoul, Korea
Contact Person	Ms. Lin Xiaoming
Title	Quality Manager
Email	rd5@ulikebeauty.com
Application Correspondent	
Company Name	PUREVISION AI, INC.
Address	111 Town Square Place, Ste 1203, Jersey City, New Jersey
Contact Person	Mr. Bryan Wong
Title	Associate
Telephone	+1 888 768 1688
Email	bryan@purefda.com

2. Subject Device Information

Trade Name	IPL Hair Removal Device
Classification Name	Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Review Panel	General & Plastic Surgery
Product Code	ONF

Regulation Class	2
Regulation Number	878.4810

3. Predicate Device Information

Predicate device I – III:

Predicate Device	I	II	III
Sponsor	Kam Yuen Plastic Products Ltd	CyDen Limited	SHASER, INC.
Device Name	Aimanfun Lumea Comfort	iPulse SmoothSkin Gold Hair Removal System	SHASER V-MINI RX
510(k) Number	K190820	K160968	K132170
Product Code	ONF	OHT	ONF
Regulation Number	878.4810	878.4810	878.4810
Regulation Class	2	2	2

4. Device Description

IPL Hair Removal Device, Model: UI04A, UI04B, UI04C, is a light-based device for long-term hair removal. It is intended for the removal of unwanted hair and permanent reduction in hair regrowth. Ideal body areas include the underarms, bikini line, arms and legs. The device used the IPL technology with lower energy level, including 5 Levels of output energy. Intense Pulsed light technology can achieve long-term hair removal results at a fraction of the energy level used in other light -based hair removal equipment.

The size of the device is about 60*38*169.86mm (W x D x H). The device incorporates Intense Pulse Light (IPL) technology. The purpose of the light is to heat the root where the hair grows.

The device contains a Xenon Lamp and a skin proximity sensor to detect appropriate skin contact. If the IPL Hair Removal Device is not properly applied to the treatment area (in full contact with the skin), the device cannot be triggered a pulse emitting.

5. Intended Use / Indications for Use

The IPL Hair Removal Device (Model: UI04A, UI04B, UI04C) is indicated for patient removal of unwanted hair by using a selective photothermal treatment under the direction of a physician，after training by a healthcare professional. The IPL Hair Removal Device is also intended for permanent reduction in unwanted hair.

6. Design

IPL Hair Removal Device consists of main unit and adaptor. It is a portable device for the permanent reduction of hair growth based on Intense Pulsed Light (IPL) which is a xenon lamp.

The size of the device is about 60*38*169.86mm (W x D x H). The device incorporates Intense Pulse Light (IPL) technology. The purpose of the light is to heat the root where the hair grows.

The device contains a Xenon Lamp and a skin proximity sensor to detect appropriate skin contact. If the IPL Hair Removal Device is not properly applied to the treatment area (in full contact with the skin), the device cannot be triggered to emit a pulse.

7. Materials

There is one part of patient directly contacting component in the subject device as the following list.

Component of Device requiring Biocompatibility	Material of Component	Body Contact Category (ISO 10993-1)	Contact Duration (ISO 10993-1)
Unit housing	ABS	Surface-contacting device: skin	Maximum 30 minutes(< 24

			hours)

The Nature of body contact is surface, skin contact. And the contact duration is less than 24 hours. According to Table 1 - Initial evaluation tests for consideration in ISO 10993-1, the applicable biological effect is:

- Cytotoxicity
- Sensitization
- Irritation or intracutaneous reactivity

8. Physical characteristics

Basic Unit Characteristics	
Main Unit Dimension	60*38*169.86mm
Unit housing material	ABS
Indicator	Indicates power information/skin detection information, energy level information.
Environment for operation	Temperature: 15-30°C Humidity: 10%-90%
Storage and Transport Conditions	Temperature: -10-60°C Humidity: 5%-90%
Compliance with Voluntary Standards	Yes. Comply with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-57.
Patient leakage current	Comply with IEC 60601-1
Power Source	Supplied by external adapter
Software/Firmware/Microprocessor Control?	Yes
Specification	

Output Intensity Level	5 levels
Output energy	2-6J/cm^2
Emitted Light Spectrum	550-1200nm
Pulse width range	0.54-3.00ms
Power Supply	External power
Technology	IPL

9. Test Summary

IPL Hair Removal Device, Model: UI04A has been evaluated the safety and performance by lab bench testing as following:

IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 2012 +A1:2012

IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, 2014

IEC 60601-1-11:2015 Medical Electrical Equipment –Part 1: General Requirements for Basic Safety and Essential Performance –Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment

IEC 60601-2-57:2011 Medical electrical equipment –Part 2-57: Particular requirements for the basic safety and essential performance of non-laser source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

ISO 10993-5:2009/(R) 2014, Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity.

ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff

10. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of IPL Hair Removal Device, model: UI04A, UI04B, UI04C is substantially equivalent to the predicate devices quoted above.

IPL Hair Removal Device relies on the same technology as both predicate devices: Intense Pulsed Light (IPL). Their energy source is the same: Xenon Arc Flashlamp.

The safety and efficacy of IPL treatment for hair reduction are governed by the following parameters:

• Wavelength of the emitted light (spectrum): Defines the interaction with specific chromophores (the part of the molecule responsible for its color) such as melanin, hemoglobin and water. IPL Hair Removal Device and the predicate devices utilize the same spectrum(550-1200nm).

• Fluence/flux – defines the energy per area (e.g. joules per cm^2) for the treatment. IPL Hair Removal Device and the predicate devices deliver the same maximum energy (6 J/cm2).

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Conclusion:

The subject device “IPL Hair Removal Device, Model: UI04A, UI04B, UI04C” is substantial equivalent to all predicate devices.